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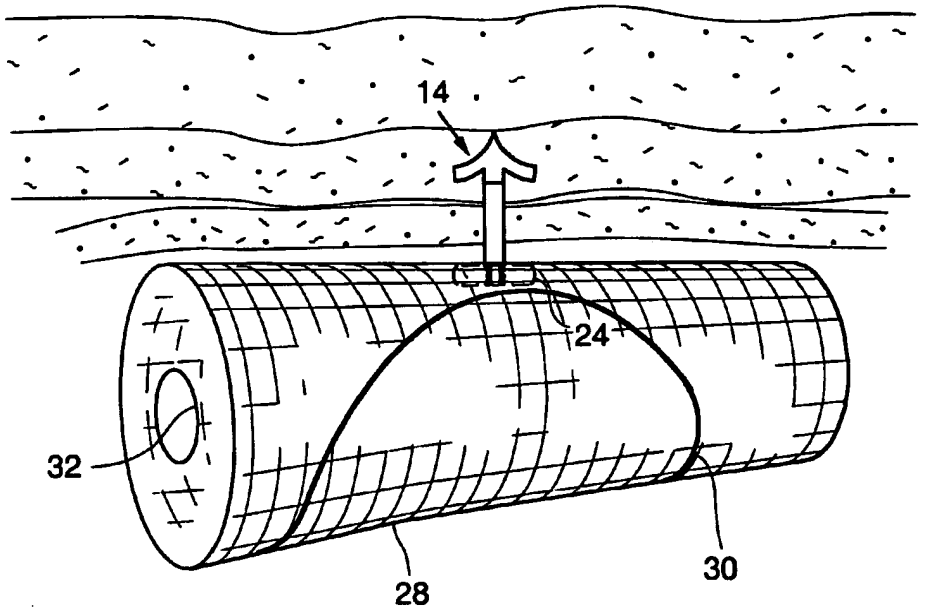

(57) Abstract: A gastric implant system includes a gastric implant such as a restrictive pouch or a gastric balloon, an anchor passable through the mouth and stomach and further through the stomach wall into engageable with abdominal wall tissue. When the anchor is engaged to abdominal wall tissue, the stomach wall and abdominal wall are brought into contact with one another such that a proximal portion of the anchor extends into the stomach interior while a distal portion of the anchor remains engaged to the abdominal wall. A locking element coupled to the proximal section of the anchor is used to maintain contact between the stomach wall and abdominal wall. The gastric implant is advanced through the oral cavity into the stomach and is coupled to the anchor.

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SYSTEM AND METHOD FOR ANCHORING STOMACH IMPLANT

TECHNICAL FIELD OF THE INVENTION

The present invention relates generally to the field of systems and methods for performing endoscopic surgery, and specifically to systems and methods for endoscopic anchoring of implants within the stomach.

BACKGROUND

Several of Applicant's prior applications, including WO 2005/037152, U.S. Patent 6,675,809, and U.S. Application No. 11/439,461, Filed May 23, 2006, Attorney Docket BARO 910 (each of which is incorporated herein by reference in its entirety) describe methods according to which medical implants are coupled to tissue within the stomach. According to these applications, devices for inducing weight loss (e.g. by restricting and/or obstructing flow of food into the stomach, and/or by occupying a portion of the stomach volume and/or or by limiting absorption of nutrients by the stomach and/or small intestine) may be coupled to the stomach tissue, or to tissue tunnels or plications formed from stomach tissue.

Other types of implants may be coupled to stomach tissue, plications or other tissue structures for a variety of purposes. These implants include, but are not limited to gastric space occupiers, prosthetic valves for the treatment of gastro-esophageal reflux disease, gastric stimulators, pH monitors and drug eluting devices that release drugs, biologics or cells into the stomach or elsewhere in the GI tract. Such drug eluting devices might include those which release leptin (a hormone which creates feelings of satiety), Ghrelin (a hormone which creates feelings of hunger), octreotide (which reduces Ghrelin levels and thus reduces hunger), Insulin, chemotherapeutic agents, natural biologics (e.g. growth factor, cytokines) which aid in post surgery trauma, ulcers, lacerations etc. Still other implants might be of a type which might provide a platform to which specific cell types can adhere, grow and provide biologically-active gene products to the GI tract, and/or a platform for radiation sources that can provide a local source of radiation for therapeutic purposes, or provide a platform whereby diagnostic ligands are immobilized and used to sample the GI tract for evidence of specific normal or pathological conditions, or provide an anchor point for imaging the GI tract via cameras and other image collecting devices.

The present application describes a new system and method for retaining implants within the stomach. According to the disclosed and illustrated procedure, an anchor is passed endoscopically from within the stomach through the stomach wall and is embedded in the tissue of the abdominal wall. The anchor holds the stomach wall and abdominal wall in contact with one another. Bonding occurs between the stomach wall and abdominal wall, creating a reinforced tissue region surrounding the anchor. An implant is coupled to the anchor. Although the implant experiences significant forces due to movement of the stomach and passage of food and liquid through the stomach, the anchor attachment is sufficiently strong to retain the implant without unintended detachment.

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1-5 are a sequence of schematic views showing a portion of a stomach wall and a portion of an abdominal wall, in which:

Fig. 1 illustrates endoscopic implantation of an anchor through the stomach wall and into the abdominal wall.

Fig. 2 illustrates the step of locking the abdominal wall and stomach wall in contact with one another.

Fig. 3 illustrates the step of coupling an implant to the anchor.

Figs. 4 and 5 illustrate the steps of deploying the implant to its expanded state, removing the spacer and adjusting the orifice size of the implant.

DETAILED DESCRIPTION

A method of implanting a gastric implant will be described in connection with Figs. 1-5. The method will be described in the context of a restrictive device implantable within the stomach to restrict the flow of food into the stomach, although any other gastric implant including, but not limited to, those listed above may utilize a similar procedure.

At the start of the procedure, the stomach is preferably insufflated to provide working space within the stomach and to move the stomach wall closer to the abdominal wall. A flexible endoscope 10 is passed through the mouth and esophagus into the stomach. Under endoscopic visualization, the stomach is palpated until a desired location for an anchor is located. This step may be performed in a manner similar to known steps for locating a position for a percutaneous gastronomy device.

An anchor deployment catheter 12 is passed into the stomach via the esophagus and advanced to an area of the stomach wall near the target anchor site. Disposed within the anchor deployment catheter 12 is an anchor 14 having a distal end that is compressed within the catheter 12 but expandable once released from the deployment catheter 12. In one example shown in the drawings, the anchor may have a "treble hook" dart type configuration with an elongate body 16 and laterally extending barbs 18 similar to those found on a fishing lure. A tether 20 is connected to the elongate body 16 and extends through the catheter 20.

The catheter 12 is positioned with its distal end in contact with the stomach wall, and the anchor 14 is driven from the stomach through the stomach wall and into the abdominal wall, embedding the anchor in the abdominal wall. The anchor may be driven by fluid or gas pressure delivered to the anchor, or using a mandrel coupled to the anchor. Alternatively, the anchor may be compressed within a hollow needle that is advanced through the stomach wall and abdominal wall, and then released from the hollow needle once the needle is positioned within the abdominal fascia.

When the anchor exits the catheter 12, the barbs 18 expand to their extended positions, causing the anchor to engage with the surrounding tissue. At least a portion of the elongate body 16 remains within the stomach. With tension applied to the tether, a spacer 22 threaded onto the tether 20 is advanced into contact with the stomach wall to impart sufficient pressure against the stomach wall to draw the stomach wall and abdominal wall in contact with one another. A locking button 24, also threaded onto the tether, is advanced behind the spacer 22 and locked against the body 16 or the tether to maintain the position of the spacer 22 and to retain contact between the stomach wall and abdominal wall. Locking features for this purpose may include teeth 25 on the body 16 or tether and corresponding engaging features on the locking button (e.g. similar to a "zip-tie" arrangement). The catheter 12 is removed, leaving the anchor 14, tether 20, spacer 22 and locking button 24 in place as shown in Fig. 2.

Next, an implantation catheter 26 for a restrictive device is advanced over the tether 20 while tension is maintained on the tether. Inside the implantation catheter 26 is a tubular restrictive device 28 in a compressed position. The restrictive device 28 may be a self-expandable device retained in the compressed position by a tear-away sheath or biodegradable/absorbable sheath, or it may be one requiring active expansion using a balloon or other expandable device positioned within its lumen.

The restrictive device 28 is anchored to the locking button 24, preferably without deploying the restrictive device 28 to its expanded position. Delaying expansion of the

restrictive device 28 is preferred because it allows the anchor attachment to heal and strengthen before it is subjected to the increased stresses imparted as a result of food flowing through the restrictive device. The implantation catheter 26 is withdrawn from the body and the tether 20 is cut or removed from the anchor.

After an appropriate healing time, which may be on the order of five days, flexible endoscope 10 is advanced back into the stomach. Associated instruments are used to remove the spacer 22, leaving a gap between the locking button 24 and the stomach wall as shown in Fig. 4. Removing the spacer 22 minimizes the likelihood or erosion of the stomach wall by the spacer. In one embodiment, the spacer might be have a thickness of approximately 3 cm or more, thus leaving a gap of at least 3 centimeters between the locking button 24 and the stomach wall upon removal of the spacer. The restrictive device 28 is deployed to its expanded position as shown in Fig. 5. The orifice size (e.g. the cross-sectional area of the proximal or distal orifice 32 and/or lumen) of the restrictive device 28 is adjusted as needed to provide a desired amount of restriction sufficient to lead to an appropriate weight loss for the patient. Some methods for controlling the orifice size of the restrictor are disclosed in Applicant's U.S. Application 2004-0158331, which is incorporated herein by reference. The restrictive device 28 may include one or more stabilizing bars/struts 30 to maintain stability of the device within the stomach and to keep the proximal orifice of the implant oriented towards the esophagus for receipt of ingested food.

The disclosed system can be packaged with instructions for use instructing the user to use the system according to methods disclosed herein.

It should be recognized that a number of variations of the above-identified embodiments will be obvious to one of ordinary skill in the art in view of the foregoing description. Accordingly, the invention is not to be limited by those specific embodiments and methods of the present invention shown and described herein. Rather, the scope of the invention is to be defined by the following claims and their equivalents.

All patents and applications referred to herein, including for purposes of priority, are incorporated herein by reference.

CLAIMS

We claim:

1. A method of anchoring a stomach implant, comprising the steps of:

introducing an anchor transorally into a stomach;

passing the anchor through a wall of the stomach and engaging the anchor to an abdominal wall, a portion of the anchor remaining within the stomach;

positioning a stomach implant within the stomach; and

coupling the stomach implant to the portion of the anchor within the stomach.

2. The method of claim 1, further including positioning the stomach wall and abdominal wall into contact with one another.

3. The method of claim 2, further including retaining contact between the stomach wall and abdominal wall using an element on the portion of the anchor within the stomach.

4. The method of claim 2, further including allowing tissue growth to occur between the stomach wall and abdominal wall.

5. The method of claim 4, wherein the stomach implant is coupled to the anchor after allowing tissue growth to occur.

6. The method of claim 1, wherein passing the anchor includes piercing the stomach wall using the anchor.

7. The method of claim 1, wherein the method includes positioning the anchor within a hollow needle, and wherein passing the anchor includes piercing the stomach wall using the hollow needle.

8. The method of claim 1, wherein engaging the anchor to the abdominal wall includes engaging the anchor and fascia of the abdominal wall.

9. The method of claim 1, wherein positioning a stomach implant includes positioning a flow restrictive device.

10. The method of claim 1, wherein positioning a stomach implant includes positioning a gastric space occupier.

11. A gastric implant system, comprising:

a cannula extendable through a mouth into a stomach;;

an anchor;

a gastric implant; and

instructions for use instructing the user to extend the cannula through a mouth in to a stomach, pass an anchor through the cannula and through a stomach wall and to engage the anchor to an abdominal wall with a portion of the anchor extending into the stomach, and to couple the gastric implant to the portion of the implant extending into the stomach.

12. The gastric implant system of claim 11, wherein the gastric implant is a restrictive orifice for treatment of obesity.

13. The gastric implant system of claim 11, wherein the gastric implant is an obstructive orifice for treatment of obesity.

14. The gastric implant system of claim 11, wherein the anchor includes a lock, and wherein the instructions for use include instructions to bring the stomach wall into contact with the abdominal wall, and engage the lock within the stomach to maintain contact between the stomach wall and the abdominal wall.

15. The gastric implant system of claim 14, wherein the anchor includes an distal tissue engaging element and a proximal portion proportioned to extend through a stomach wall and into a stomach when the distal portion is engaged with abdominal wall tissue, and wherein the lock includes a collar slidable on the proximal portion into abutment with stomach wall tissue and lockable to the proximal portion to retain the collar position in abutment with the stomach wall.

16. The gastric implant of claim 11, further including a tether coupled to the anchor, the tether proportioned to extend from the proximal section through the esophagus and stomach and out of the oral cavity when the anchor is engaged with abdominal wall tissue.

17. The gastric implant of claim 15, wherein the gastric implant is attachable to the collar.

18. The gastric implant of claim 11, further including a detachable spacer between the collar and the tissue engaging element.

19. A gastric implant system including:

a gastric implant;

an anchor having a distal portion engageable with abdominal wall tissue within a living body, and a proximal section proportioned to extend from the distal portion, through a stomach wall and into a stomach when the distal portion is engaged with abdominal wall tissue; and

a locking element coupled to the proximal section of the anchor, the locking element having an unlocked position in which the locking element is moveable relative to the anchor into a position in abutment with an interior surface of a stomach wall, and a locked position in which the locking element engages a portion of the anchor.

20. The implant system of claim 19, wherein the gastric implant is a restrictive implant for treating obesity.

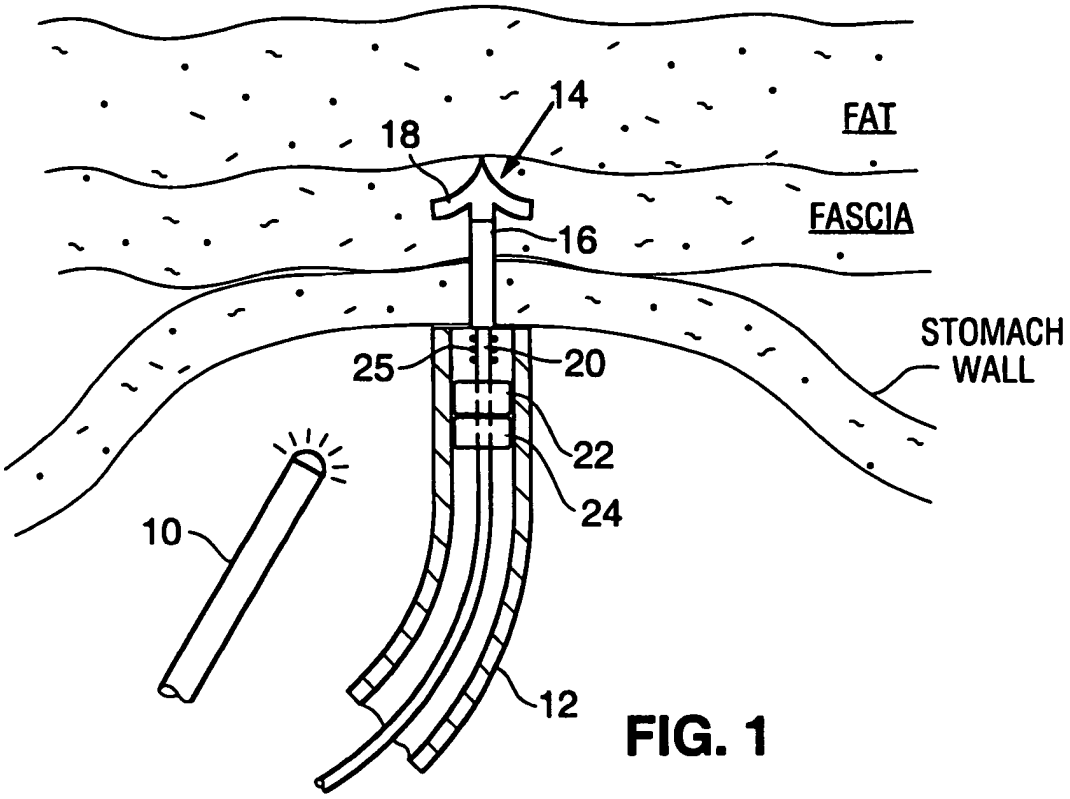
21. The implant system of claim 20, wherein the gastric implant is an obstructive implant for treating obesity.

22. The implant system of claim 19, wherein the distal portion of the anchor includes an expandable tip section.

23. The implant system of claim 19, further including a tether coupled to the proximal section, the tether proportioned to extend from the proximal section through the esophagus and stomach and out of the oral cavity when the anchor is engaged with abdominal wall tissue.

24. The implant system of claim 19, wherein the proximal section includes an elongate member and wherein the locking element includes a collar slidable on the elongate member.

25. The implant system of claim 24, wherein the collar is lockable to features on the elongate member.


14
18
FAT
FASCIA
16
STOMACH
WALL
25
20
22
24
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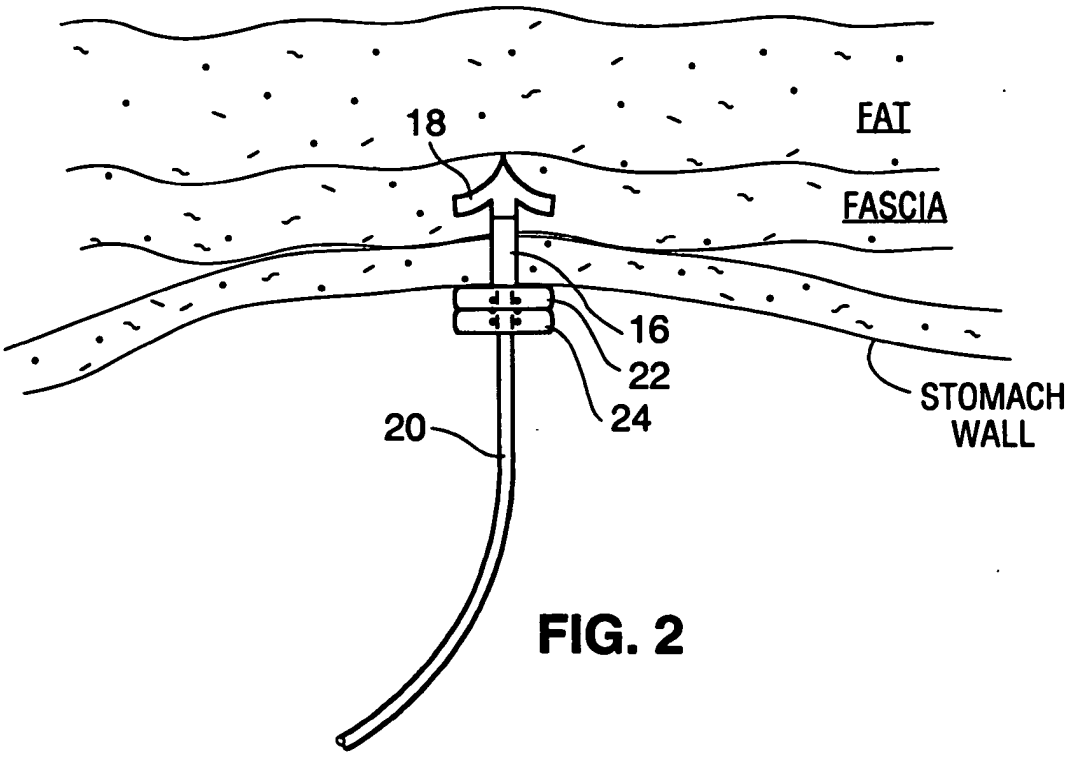
12

FIG. 1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FAT
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FIG. 2

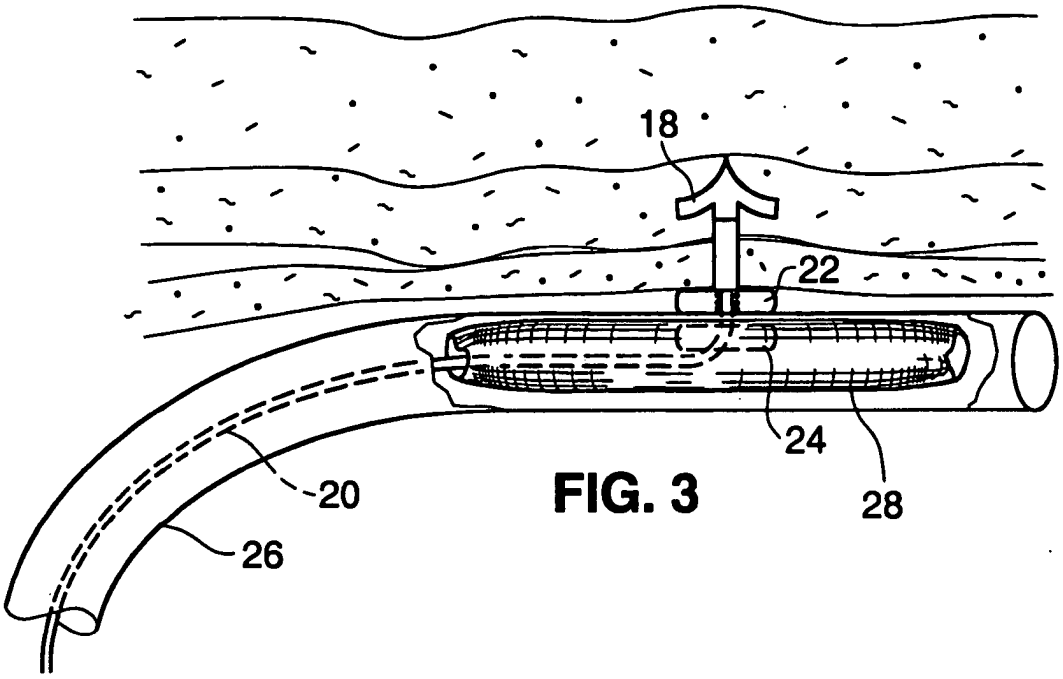

FIG. 3

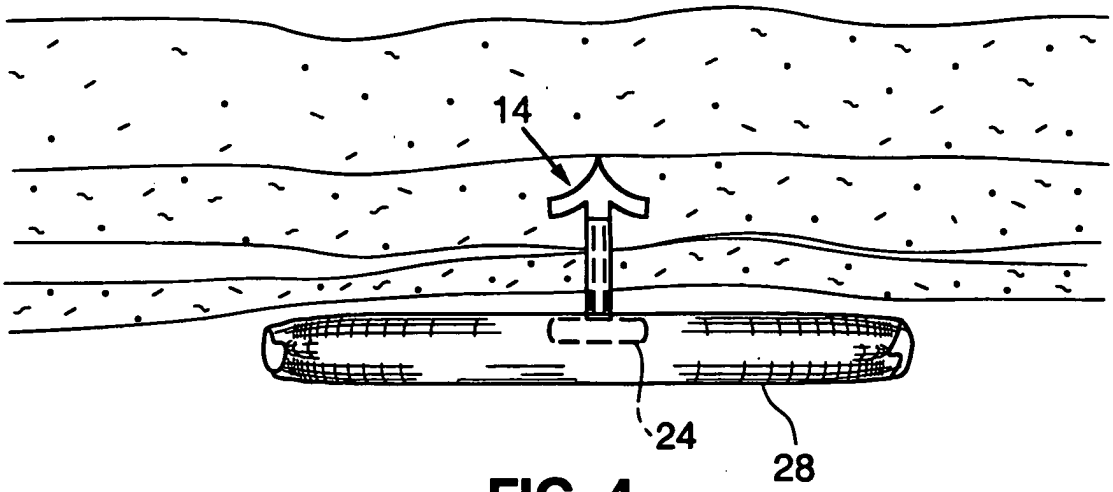

FIG. 4

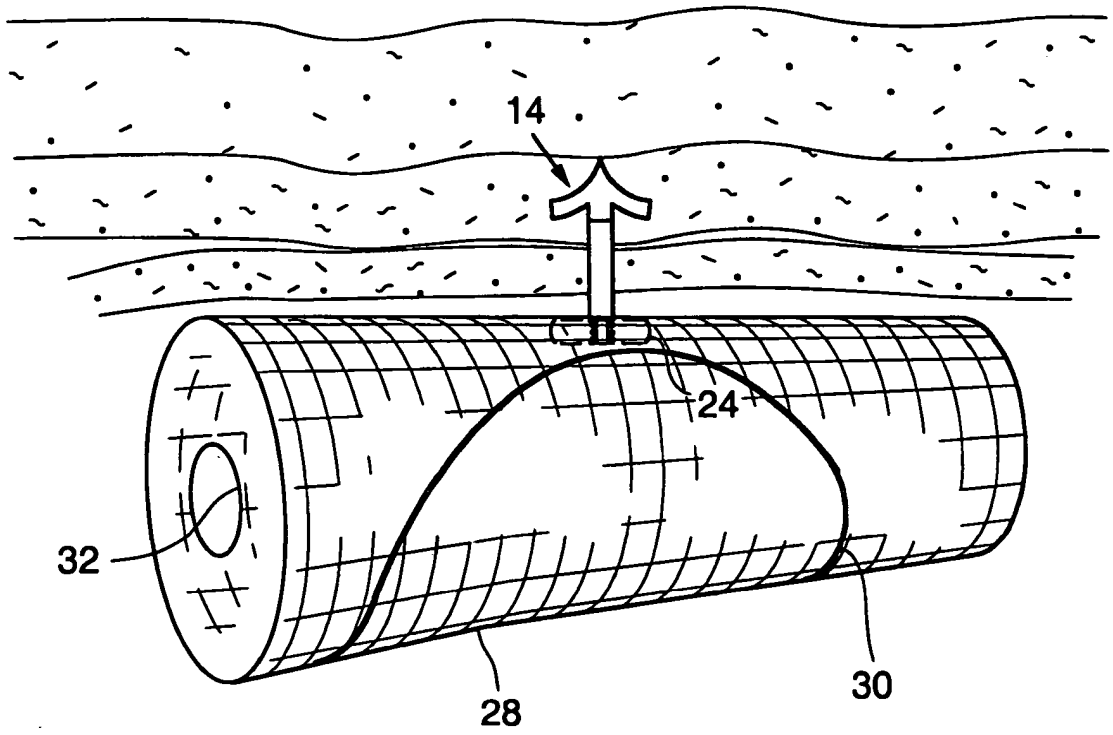

FIG. 5